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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,960	07/25/2003	Ary S. Chernomorsky	RUBI5873	2271
22430	7590	05/31/2005	EXAMINER	
YOUNG LAW FIRM A PROFESSIONAL CORPORATION 4370 ALPINE ROAD SUITE 106 PORTOLA VALLEY, CA 94028			DAWSON, GLENN K	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 05/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No. 10/627,960	Applicant(s) CHERNOMORSKY ET AL.	
	Examiner Glenn K. Dawson	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2005.
- 2a) ☐ This action is FINAL.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) 34-39 and 71-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19, 23, 24, 28-33, 40-57, 61, 62 and 64-70 is/are rejected.
- 7) ☒ Claim(s) 20-22, 25-27, 58-60 and 63 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
 - 1. ☐ Certified copies of the priority documents have been received.
 - 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>08-15-03; 12-29-03</u> <u>3/9/05</u> | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Claims 34-39 and 71-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04-22-2005.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 11-15, 18 and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Vidal, et al.-5334216.

Vidal discloses a collagen hemostatic plug having portions of different densities which would inherently cause the two portions to have different pore characteristics such as pore density or pore orientation. The plug is made out of collagen, gelatin and PGA material as well as thrombin. The plug's portions are constructed so that the portions have different swelling characteristics upon receipt of body fluids. See col. 2 lines 3-56; col. 4 lines 45-51.

Claims 1-4, 12, 13, 15, 18 and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Urbanski-6183496.

Urbanski discloses a collagen hemostatic plug made of collagen filaments. The two sheets that make up the plug have different densities causing different pore characteristics. The plug will therefore have portions which swell differently upon receipt of body fluids. See col. 5 lines 52-63; col. 6 lines 3-20; col. 7 lines 57-61.

Claims 1-4, 12, 13, 15-19, 28-30, 40-42, 50, 51, 53-57, 64-66 and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Krajicek-5522840.

Krajicek discloses a swellable collagen plug made out of two facing layers. The two layers have different degrees of cross-linking by the tanning process which causes the two portions to swell differently upon receipt of body fluids. See col. 3 lines 7-38.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 31, 32, 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krajicek-'840 in view of Li-6090996.

Krajicek discloses the invention as claimed with the exception of the type of cross-linking. Li discloses that it was known to cross-link collagen matrixes by formaldehyde, glutaraldehyde or a dehydrothermal process. See col. 1 lines 24-30; col. 2 lines 21-31; col. 3 lines 29-64; col. 4 lines 21-29 and 48-60; and col. 5 lines 19-24. It would not have involved an inventive step to have used the cross-linking methods of Li in making the implant of Krajicek, as these methods have been shown to be effective at forming a stable matrix.

Claims 33 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krajicek-'840 in view of Rhee, et al. 5510418.

Krajicek discloses the invention as claimed with the exception of cross-linking the matrix by a combination of both cyanamide and a dehydrothermal process. As both of these methods were known, as taught by Rhee in col. 2 lines 38-45, to have used both of the cross-linking methods of Rhee in making the implant of Krajicek would not have involved an inventive step as these methods have been shown to be individually effective at forming a stable matrix, and using both would have produced a stable matrix as well.

Claims 5,8-11,23,43,46-49 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krajicek-'840 in view of Fulton, et al.-6270464.

Krajicek discloses the implant as claimed with the exception of the additives in the matrix. Fulton discloses the use of the claimed additives. See col. 2 lines 28-55 and col. 3 lines 50-60. It would not have involved an inventive step to have added the contrast agents and the bioactive agents, as these would allow for non-invasive detecting of the position of implantation of the plug and would allow for the clotting of blood and the prevention of infection.

Claims 5-7,10,11,14,23,24,43,44,45,48,49,52,61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krajicek-'840 in view of Sing, et al.-6183497.

Krajicek discloses the invention as claimed with the exception of the additives. Sing discloses the use of radiopaque materials, radioactive materials and thrombin. See col. 2 lines 52-59; col. 3 lines 11-20 and 45-60; and col. 8 lines 24-38. It would not have involved an inventive step to have added the additives of Sing to the plug of Krajicek, as these materials allow for blood clotting, treatment of cancerous cells and non-invasive imaging of the location of the plug in the patient's body.

Allowable Subject Matter

Claims 20-22,25-27,58-60 and 63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or fairly suggest the implant of claim 1 including an

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internal reservoir to contain a dye, pigment or therapeutic agent; a third porous portion forming with the first and second portions a predetermined pore density gradient; an implant having portions with differing cross-linking densities; a method of mapping a lymphatic system following a cavity generating procedure, including providing an implant having a collagenous matrix with non-uniform cross-linking density and a dye or pigment which swells non uniformly, implanting it into the cavity, closing the cavity, causing the dye or pigment to be released to propagate through the lymph system and visualizing the pigment in the lymph system.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 08-15-2003, 12-29-2003 and 03-09-2005 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K. Dawson whose telephone number is 703-308-4304. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 703-308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Glenn K Dawson
Primary Examiner
Art Unit 3731

Gkd
27 May 2005